

## REMARKS

Claims 34-49 and 85-113 were pending in the present application before entry of the present amendment. In the Office Action of October 16, 2006, claims 93-113 have been withdrawn from consideration. However, Applicants note that claim 113 is directed a pharmaceutical composition, *i.e.*, it falls within elected Group III. Applicants, therefore, respectfully request that claim 113 be examined together with the claims 34-49 and 85-92.

Claims 35, 44, 45, and 86 have been amended to clarify that the references to multiple sequences are intended as a listing of multiple alternatives.

Claim 89 has been amended to clarify that the antibody is supposed to bind to an antigen of the listed viruses.

Claims 49 and 93-112 have been canceled without prejudice. Applicants reserve the right to prosecute the subject matter of claims 49 and 93-112 in one or more related applications.

No new matter has been introduced. Claims 34-48, 85-92, and 113 will be pending upon entry of the present amendment.

### **I. The Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph, Should Be Withdrawn**

Claims 35, 44, 45, and 86 are rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as being indefinite. In particular, the Office Action states that where the claims recite multiple sequences, it is not clear whether all sequences together or only one individual sequence is a claim limitation.

Applicants have amended claims 35, 44, 45, and 86 to clarify that the references to multiple sequences are intended as a listing of multiple alternatives. In particular, these claims have been amended to recite that the amino acid sequence is any one of the recited SEQ ID NOs. Applicants request that the rejection of claims 35, 44, 45, and 86 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, be withdrawn in view of the present amendment.

Claim 89 is rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as being indefinite. In particular, the Office Action states that it is not clear what the antibody is supposed to bind to.

As suggested by the Examiner, Applicants have amended claim 89 to clarify that the antibody is supposed to bind to an antigen of the listed viruses. Applicants request that the

rejection of claims 89 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, be withdrawn in view of the present amendment.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

### **A. THE REJECTION OVER JOHNSON, VAN DEN HOOGEN, AND Q91F55 SHOULD BE WITHDRAWN**

Claims 34, 37, 39-42, 45-47, 49, 85, and 90-92 are rejected under 35 U.S.C. § 103(a) as being obvious over published U.S. Patent serial no. 09/848,390 (“Johnson”) in view of van den Hoogen et al., 2001, *Nature Medicine* 7(6):719-724 (“van den Hoogen”) and UniProtKB/TrEMBL entry Q91F55 (“Q91F55”).<sup>1</sup> In particular, the Office Action states that it would have been obvious to combine the combination therapy of Johnson with the teachings relating to hMPV of van den Hoogen to arrive at the presently claimed invention. Applicants respectfully disagree because (i) there is no suggestion in the cited art to develop the presently claimed compositions; and (ii) not all elements of the presently claimed compositions are found in the cited art.

#### **The Legal Standard**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P. 2143.

Prior art references may be combined to render an invention obvious under 35 U.S.C. § 103, however, the teachings of references can be combined only if there is some suggestion or incentive to do so. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1575 (Fed. Cir. 1984). The teaching or motivation to combine prior art references must be “clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence.” *In re Dembiczak*, 173 F.3d 994, 999 (Fed. Cir. 1999).

The Federal Circuit has expressly indicated that a *prima facie* case of obviousness requires “objective evidence of record” demonstrating that there is prior art that teaches or

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<sup>1</sup> It is noted that claim 49 has been canceled by the present Amendment. Thus, the rejection with respect to claim 49 is moot.

suggests combining the asserted references as proposed. *In re Lee*, 277 F.3d 1338, 1341 (Fed. Cir. 2002). More specifically, the motivation to combine references originate from one of three sources: the nature of the problem to be solved, the teachings of the prior art, or the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Consequently, the reason or suggestion in the art for carrying out the invention, must originate from a source other than the knowledge learned from the Applicant's disclosure (*In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)), and care must be exercised not to use the Applicant's disclosure to fill in the gaps in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Grabiak*, 769 F.2d 729 (Fed. Cir. 1985).

Further, an obviousness rejection cannot be based on inherent disclosure in a prior art reference. The Court of Customs and Patent Appeals stated "the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966).

#### Johnson And Van Den Hoogen Do Not Teach All Claim Limitations

Johnson discloses a therapeutic composition comprising an anti-RSV antibody and an antiviral agent having therapeutic value against, *e.g.*, diseases caused by PIV. Van den Hoogen discloses the isolation and characterization of hMPV. Q91F55 discloses merely the amino acid sequence of hMPV F protein. However, neither reference explicitly discloses an antibody that binds immunospecifically to an hMPV antigen. At best, van den Hoogen's discussion of the inoculation of ferrets and guinea pigs (p. 720, left col., 2<sup>nd</sup> full paragraph) provides inherent disclosure of a method for the generation of such an antibody. It is improper, however, to rely on inherent disclosure in a reference for an obviousness rejection. *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966). Similarly, there is no explicit disclosure in the cited art of an antibody that immunospecifically binds to the F protein of hMPV. Thus, even the combination of all the cited references fails to disclose the claim limitations of **claim 34.**

#### No Motivation to Combine Johnson And Van Den Hoogen

Moreover, there is no motivation in the art to combine the teachings of van den Hoogen and Johnson. The van den Hoogen and Johnson disclose independent and unrelated aspects of the very large subject matter of viruses. Van den Hoogen relates to the isolation and discovery of hMPV, while Johnson relates to compositions and uses of therapeutic

compositions for the treatment of RSV infections. A person skilled in the art would lack the motivation to combine these two references.

The Dependent Claims

As discussed above, claim 34 is not made obvious by the cited references because the cited references fail to teach all the claim limitations of claim 34 and because there is no motivation to combine these references that can be found in the cited art. Claims 37, 39-42, 45-47, 85, and 90-92 incorporate all the claim limitations of claim 34 via their dependencies from claim 34. Accordingly, these dependent claims are also not obvious over the cited art.

**B. THE REJECTION OVER JOHNSON, VAN DEN HOOGEN, GAZUMYAN, IMPACT, AND O55887 SHOULD BE WITHDRAWN**

Claims 34, 37-42, 48-49, 85-88, and 90-92 are rejected under 35 U.S.C. § 103(a) as being obvious over published U.S. Patent serial no. 09/848,390 (“Johnson”) in view of van den Hoogen et al., 2001, *Nature Medicine* 7(6):719-724 (“van den Hoogen”), Gazumyan et al. 2000, *Current Pharmaceutical Design* 6:525-546 (“Gazumyan”), The IMpact-RSV Study Group, 1998, *Pediatrics* 102(3):531-537 (“IMpact”) and NCBI accession no. O55887 (“O55887”).<sup>2</sup>

The Cited Art Fails To Teach All Claim Limitations

With regard to **claim 34**, neither Johnson nor van den Hoogen teach antibodies against an hMPV antigen. None of the additional references, Gazumyan, IMpact, or O55887, cures this deficiency. Gazumyan is concerned with agents for the treatment of RSV. Similarly, IMpact is dedicated to a trial with Palivizumab, an anti-RSV antibody. O55887 merely discloses the amino acid sequence of the F protein of human PIV. Thus, neither any of the references individually nor the combination of the cited art discloses all the claim limitations.

The Examiner contends that one would have been motivated to make antibodies against the F protein of hMPV because Gazumyan teaches that the F glycoprotein is one of the major virus-neutralizing antigens. This statement, however, relates to RSV. Again, there is no explicit teaching in the art of immunospecific anti-hMPV antibodies, let alone antibodies that bind immunospecifically to the F protein of hMPV.

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<sup>2</sup> It is noted that claim 49 has been canceled by the present Amendment. Thus, the rejection with respect to claim 49 is moot.

### The Dependent Claims

As discussed above, claim 34 is not made obvious by the cited references because the cited references fail to teach all the claim limitations of claim 34. Claims 37-42, 48, 85-88, and 90-92 incorporate all the claim limitations of claim 34 via their dependencies from claim 34. Accordingly, these dependent claims are also not obvious over the cited art.

### C. THE REJECTION OVER JOHNSON, VAN DEN HOOGEN, GAZUMYAN, IMPACT, O55887, AND LI SHOULD BE WITHDRAWN

Claims 34-36 are rejected under 35 U.S.C. § 103(a) as being obvious over published U.S. Patent serial no. 09/848,390 (“Johnson”), van den Hoogen et al., 2001, *Nature Medicine* 7(6):719-724 (“van den Hoogen”), Gazumyan et al. 2000, *Current Pharmaceutical Design* 6:525-546 (“Gazumyan”), The IMpact-RSV Study Group, 1998, *Pediatrics* 102(3):531-537 (“IMpact”), and NCBI accession no. O55887 (“O55887”), in view of WO96/40945 (“Li”).

### The Cited Art Fails To Teach All Claim Limitations

With regard to **claims 34**, Li fails to cure the shortcomings of the prior art that have been discussed above. Li relates to the F protein of RSV but is silent as to hMPV. Thus, none of the references individually or the combination disclose all the claim limitations.

### The Dependent Claims

As discussed above, claim 34 is not made obvious by the cited references because the cited references fail to teach all the claim limitations of claim 34. Claims 35 and 36 incorporate all the claim limitations of claim 34 via their dependencies from claim 34. Accordingly, these dependent claims are also not obvious over the cited art.

### D. THE REJECTION OVER JOHNSON, VAN DEN HOOGEN, GAZUMYAN, IMPACT, O55887, AND SEAL SHOULD BE WITHDRAWN

Claims 34, 40, and 43-44 are rejected under 35 U.S.C. § 103(a) as being obvious over published U.S. Patent serial no. 09/848,390 (“Johnson”), van den Hoogen et al., 2001, *Nature Medicine* 7(6):719-724 (“van den Hoogen”), Gazumyan et al. 2000, *Current Pharmaceutical Design* 6:525-546 (“Gazumyan”), The IMpact-RSV Study Group, 1998, *Pediatrics*

102(3):531-537 (“IMpact”), and NCBI accession no. O55887 (“O55887”), in view of Seal et al., 2000, Virus Research 66:139-147 (“Seal”).

The Cited Art Fails To Teach All Claim Limitations

With regard to **claims 34**, Seal fails to cure the shortcomings of the prior art that have been discussed above. Seal relates to the F protein of APV but is silent as to hMPV. Thus, none of the references individually or the combination disclose all the claim limitations.

The Dependent Claims

As discussed above, claim 34 is not made obvious by the cited references because the cited references fail to teach all the claim limitations of claim 34. Claims 40, and 43-44 incorporate all the claim limitations of claim 34 via their dependencies from claim 34. Accordingly, these dependent claims are also not obvious over the cited art.

E. THE REJECTION OVER JOHNSON, VAN DEN HOOGEN, GAZUMYAN, IMPACT, O55887, AND VAINIONPAA SHOULD BE WITHDRAWN

Claims 34, 85, and 89 are rejected under 35 U.S.C. § 103(a) as being obvious over published U.S. Patent serial no. 09/848,390 (“Johnson”), van den Hoogen et al., 2001, Nature Medicine 7(6):719-724 (“van den Hoogen”), Gazumyan et al. 2000, Current Pharmaceutical Design 6:525-546 (“Gazumyan”), The IMpact-RSV Study Group, 1998, Pediatrics 102(3):531-537 (“IMpact”), NCBI accession no. O55887 (“O55887”), in view of Vainionpaa and Hyypia, 1994, Clinical Microbiology Reviews 7(2):265-275 (“Vainionpaa”).

The Cited Art Fails To Teach All Claim Limitations

With regard to **claims 34**, Vainionpaa fails to cure the shortcomings of the prior art that have been discussed above. Vainionpaa relates to PIV but is silent as to antibodies against hMPV. Thus, none of the references individually or the combination disclose all the claim limitations.

The Dependent Claims

As discussed above, claim 34 is not made obvious by the cited references because the cited references fail to teach all the claim limitations of claim 34. Claims 85 and 89

incorporate all the claim limitations of claim 34 via their dependencies from claim 34. Accordingly, these dependent claims are also not obvious over the cited art.

### CONCLUSION

Applicants respectfully request that the remarks and amendments be entered and made of record in the present application. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Respectfully submitted,

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Laura A. Coruzzi 30,742  
Laura A. Coruzzi (Reg. No.)  
**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939

By: Jennifer J. Chioda  
Reg. No. 46,617